REMARKS

The Claims have been amended and Claim 21 added to more clearly claim the invention. Support for Claim 21 can be found in the Specification as filed, for example on page 2, lines 3-10 for the language about a defect in iron metabolism, on page 56, lines 15-20 for the correlation between brain disorder and iron metabolism, on page 34, lines 19-page 35, line 9 for the diagnostic method, and on page 42, lines 3-12 for the detection. Support for the amendments to Claim 7 can be found in the Specification as filed, for example on page 2, lines 3-10 and page 34, lines 19-27 for the method of detection. No new matter has been added herewith. The changes made to the claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined.

Rejection under 35 U.S.C.§112, first paragraph

The Examiner rejected Claims 7-9 under 35 U.S.C.§112, first paragraph for lack of enablement. More specifically, the Examiner believed that the Declaration by Dr. Kirsch was insufficient to overcome the rejection under 35 U.S.C. §112 for enablement for a number of reasons as set out below.

The Examiner believed that the Declaration was insufficient because the data presented was from a single patient. The Applicants now provide an additional Declaration providing data from three additional AD/MCI patients. The declaration clearly shows that the claimed diagnostic method is reproducible. The additional data overcomes this concern raised by the Examiner.

Further, the Examiner believed that the data presented in the immunocytochemistry micrograph was not quantitative. Although we disagree, in order to obviate this rejection, we have amended claim 7 to specifically recite that the identification is by "detecting more probe that interacts with the protein in the biological sample than would be detected in a control sample".

The Examiner also believed that the diagnosis of the patient as having Alzheimer's disease or MCI can only be made based on postmortem brain tissue analysis. While it is apparently true that definitive diagnosis can only be made in this way, enablement does not require that a definitive diagnosis be made. Rather, the law only requires that one skilled in the art would find the invention to be credible based on the information available. The standard set forth by the PTO in this Office Action would require us to wait for the subject patient to die

before we could obtain a patent. This is clearly unreasonable and beyond the standard established by law. Moreover, as noted above and discussed in the Declaration, a diagnosis of MCI and/or AD was made using the enclosed Clinical Dementia Rating (CDR - Exhibit G). The CDR is used in addition to tests which rule out other possible causes of such symptoms (see Exhibit B for example) and in addition to a geriatric assessment. These tests in addition to the CDR can provide the best possible diagnosis in the absence of post-mortem testing.

Lastly, the Examiner objects to the inclusion of Parkinson's disease in the claims and believes the association between IRP-2 and Parkinson's disease to be unsubstantiated, even in view of the statements in Dr. Kirsch's declaration. Although we believe this rejection to be incorrect, we have amended Claim 7 to remove the reference to Parkinson's so as to expedite the prosecution of the application. We retain the right to pursue a diagnostic for Parkinson's disease in a Divisional or Continuation application.

Rejection under 35 U.S.C.§112, second paragraph

The Examiner rejected Claims 7-9 under 35 U.S.C.§112, second paragraph as being indefinite for the following reasons:

Claim 7 was believed vague for recitation of "a wild type or mutant[...] IRP-2 protein (SEQ ID NO:18). The claims has been amended to clarify that SEQ ID NO:18 refers to the sequence of the wild type IRP-2 protein.

Claims 7 was believed vague as to the recitation of "MCI". The claims has been amended to read "mild cognitive impairment (MCI)".

Claim 20 was believed vague as to the recitation of what the probe interacts with and "the polynucleotide". However, Claim 20 has been canceled so the rejection is moot.

In view of the above amendments, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

Conclusion

In view of the remarks herein, it is believed that the claims are allowable. However, should the Examiner have any further questions, please contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 25, 2004

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